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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/945,379	08/31/2001	Vince Phillips	5100-0705 0019-US	2153

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EXAMINER	
HORLICK, KENNETH R	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/945,379	Applicant(s) PHILLIPS ET AL.	
	Examin r Kenneth R Horlick	Art Unit 1637	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-63* is/are rejected.

7)☒ Claim(s) *10-13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 August 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4*. (3 pages)
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is confusing because of the language "alleles differ by a single polynucleotide". It would appear that "nucleotide" is intended; clarification is required.

2. Claims 10-13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. As these claims fail to recite any further active steps not already included in the base claims, it cannot be determined what further limitations are contemplated. Clarification is required.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 5-7, 10, 11, 14-16, 27, 37-46, 53-56, and 59-62 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 2 312 747.

In brief, claim 1 is drawn to a method for assaying for an amplification product, wherein the amplification product comprises a capture sequence whose complement is not present in the unamplified target polynucleotide (i.e., the capture sequence is provided during amplification), using a molecular beacon with a fluorophore/quencher labeling system, wherein the beacon target sequence is complementary to the capture sequence present in the amplification product. Claim 37 is drawn to a method similar to claim 1, further including steps of creating such an amplification product using a primer comprising a sequence which is noncomplementary to a target sequence. Claim 62 is drawn to a complex comprising such an amplification product hybridized to such a molecular beacon probe.

GB 2 312 747 discloses the claimed methods and complex; see especially Figs. 11(a) and 11(b); pages 1-7; pages 12-13.

5. Claims 1, 5-7, 10, 11, 14-16, 27, 37-46, 53-56, and 59-62 are rejected under 35 U.S.C. 102(e) as being anticipated by Nadeau et al. (US 6,316,200).

This patent discloses the claimed methods and complex; see columns 3-11, especially column 7, lines 24-46 and the paragraph bridging columns 10 and 11.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8, 9, 12, 13, 17-20, 22-26, 28-36, 47-52, 57, 58, and 63 rejected under 35 U.S.C. 103(a) as being unpatentable over either of GB 2 312 747 or Nadeau et al. These claims are drawn to the methods as described and rejected above, with further limitations regarding particular assay reagents and conditions, for example the use of solid supports or quantitative measure of target. Claim 63 is drawn to a kit useful in performing a method such as that of claim 37.

One of ordinary skill in the art would have been motivated to modify the method of GB 2 312 747 or Nadeau et al. in the claimed manner because the additional limitations are clearly trivial and merely involve assay reagents/conditions which were well known and common knowledge in the art at the time of the invention, which would

have been expected to provide well known benefits. Regarding claim 63, kits were also clearly common knowledge in the art for facilitating the practice of methods requiring certain reagents or components; for example, a kit is disclosed in the GB document in claim 23 on page 38. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods and to make and use the claimed kit.

7. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of GB 2 312 747 or Nadeau et al., in view of Weiss et al. (US 6,207,392).

These claims are drawn to the method of claim 1 as described and rejected above, wherein the first fluorophore is a semiconductor nanocrystal.

The teachings of GB 2 312 747 and Nadeau et al. are discussed above.

Neither of these primary references discloses a semiconductor nanocrystal.

Weiss et al. disclose the use of semiconductor nanocrystals as fluorescent labels in nucleic acid assays (see especially columns 7, 12-13 and 16-28), including applications in energy transfer assays.

One of ordinary skill in the art would have been motivated to modify the method of either one of the primary references by using one or more semiconductor nanocrystals as a fluorophore because Weiss et al. taught that such nanocrystals were advantageous fluorescent labels in nucleic acid assays. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed methods.

8. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over either of GB 2 312 747 or Nadeau et al., in view of Weiss et al. (US 6,207,392), and further in view of Bawendi et al. (US 2002/0160412).

This claim is drawn to the methods as discussed and rejected above, further wherein the microsphere comprises a spectral code.

Neither of the primary references, nor Weiss et al., disclose the use of a spectral code in the context of semiconductor nanocrystals.

Bawendi et al. disclose the use of an encoding system, or "barcode", for use with semiconductor nanocrystals. One of the preferred embodiments is the use of such a system in the context of DNA identification and tracking. See especially abstract; paragraph [0013]; page 7 at paragraph [0057] to page 9, paragraph 0074].

One of ordinary skill in the art would have been motivated to apply a spectral code to the method of GB 2 312 747 or Nadeau et al., as modified by Weiss et al., because Bawedi et al. disclosed that such a code or barcode system was advantageous in identification and tracking of nucleic acids labeled with semiconductor nanocrystals. It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the claimed method.

9. No claims are free of the prior art.

10. The following are made of record as references of interest: Bruchez, Jr. et al. (US 6,500,622), Whitcombe et al. (US 6,270,967), and Nadeau et al. (US 2002/0086306).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kenneth R. Horlick, Ph.D.

Kenneth R Horlick
Primary Examiner
Art Unit 1637

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April 1, 2003